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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,080	02/27/2002	David H. Mack	018501-000840US	2006

20350 7590 05/06/2004

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EXAMINER

MARTINELL, JAMES

ART UNIT PAPER NUMBER

1631

DATE MAILED: 05/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/087,080

Applicant(s)

MACK ET AL.

Examiner

James Martinell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 8-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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Applicant's election of Group I, claims 1-7, and SEQ ID NO: 31 which encodes SEQ ID NO: 32) in the response filed February 20, 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Applicants have not explained a relationship between SEQ ID NO: 29 and 31. Accordingly, SEQ ID NO: 29 has not been examined on the merits.

Claims 8-21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the response filed February 20, 2004.

The disclosure is objected to because of the following informalities.

- (a) The numbering of the Tables is inconsistent and should be corrected. For example, Tables 1-20 are numbered consecutively and are then followed by Tables 1-20A and 1-20B.
- (b) Table 26 is a sequence listing and as such it does not comply with the sequence rules (see 37 CFR §§ 1.821-1.825 and MPEP 2420-2434) because it is not in the proper format.

Appropriate correction is required.

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. Embedded hyperlink and/or other form of browser-executable code appear in at least the following locations:

- (a) page 10, line 33 and
- (b) page 25, line 32.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are vague, indefinite, and incomplete.

- (a) The recitation of "selectively hybridizes" (claim 1) is vague, indefinite, and incomplete because the term is a relative one without a frame of reference. Whether hybridization is selective depends upon the types of sequences in the reaction mix.
- (b) The recitation of "selectively hybridizes to a sequence at least 80% identical to SEQ ID NO: 29 or 31" is vague, indefinite, and incomplete because the metes and bounds of the claim are unknowable. It cannot be determined what may "selectively" hybridize to such a large number of sequences. There are no fewer than 8.14×10^{405} nucleotide sequence insertion variations of SEQ ID NO: 31 that are 80% identical to SEQ ID NO: 31. There are 1.24×10^{145} possible sequences of 241 nucleotides length. DNA duplexes of greater than 50 base pairs are maximally stable (see Kennell (Progr. Nucl. Acid Res. Mol. Biol. 11: 259 (1971), paragraph bridging pages 260-261, cited here as of interest). The sequences embraced by the claims that contain insertions of 241 nucleotides would hybridize specifically to DNAs that have not been described in the application. Thus, the metes and bounds of the claims cannot be determined.
- (c) Claims 1 and 5 are vague and indefinite because they claim more than was elected.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There are no fewer than 8.14×10^{405} nucleotide sequence insertion variations of SEQ ID NO: 31 that are 80% identical to SEQ ID NO: 31. There are 1.24×10^{145} possible sequences of 241 nucleotides length. DNA duplexes of greater than 50 base pairs are maximally stable (see Kennell, paragraph bridging pages 260-261, cited here as of interest). The sequences embraced by the claims that contain insertions of 241 nucleotides would hybridize specifically to DNAs that have not been described in the application.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-7 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. The instant application does not disclose any connection between SEQ ID NO: 31 and colo-rectal cancer. Thus, there is no disclosed utility, nor is there a readily apparent utility for nucleic acids that contain SEQ ID NO: 31.

Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. There is no disclosed connection between SEQ ID NO: 31 and colo-rectal cancer. Thus, the method claims (1-4) are not enabled. Likewise, there is no disclosed use for the sequences, vectors, or host cells of claims 5-7.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claim 5 is rejected under 35 U.S.C. 102(a) as being clearly anticipated by Hong et al (Genesis 29: 163 (April 10, 2001)). Hong et al discloses a DNA that shares 100% sequence identity with SEQ ID NO: 31 (see the alignment attached to this Office action as Appendix A).


Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Martinell whose telephone number is (571) 272-0719. The fax phone number for Examiner Martinell's desktop workstation is (571) 273-0719. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be e-mailed to james.martinell@uspto.gov. Since e-mail communications may not be secure, it is suggested that information in such requests be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-0722.

PLEASE NOTE THE NEW FAX NUMBER

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.


James Martinell, Ph.D.
Primary Examiner
Art Unit 1631 5/4/04